510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041687

B. Purpose for Submission:
New Device

C. Analyte:
Quality Control Material (assayed and unassayed) and Calibrator Material

D. Type of Test:
NA

E. Applicant:
Abbott Laboratories

F. Proprietary and Established Names:
Abbott ARCHITECT® Estradiol Controls (LN 6C22)
Abbott ARCHITECT® Estradiol Controls (LN 2K25)
Abbott AxSYM® Estradiol Controls
Abbott FSH Controls
Abbott ARCHITECT® LH Controls
Abbott ARCHITECT® Prolactin Controls
Abbott ARCHITECT® Progesterone Controls
Abbott ARCHITECT® Estradiol Calibrators

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1660
   21 CFR 862.1150

2. Classification:
   Controls – Class I
   Calibrator - Class II

3. Product Code:
   JJX
   JIT

4. Panel:
   75 Chemistry

H. Intended Use:

1. Intended use(s):

   Abbott ARCHITECT® Estradiol Controls (LN 6C22) are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of estradiol in human serum and plasma.
   Abbott ARCHITECT® Estradiol Controls (LN 2K25) are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of estradiol in human serum and plasma.
   Abbott AxSYM® Estradiol Controls are for the estimation of test precision and the detection of systematic analytical deviations of the AxSYM system when used for the quantitative determination of estradiol in human serum.
   Abbott FSH Controls are for the verification of the precision and accuracy of the ARCHITECT, AxSYM and IMx systems when used for the quantitative determination of follicle stimulating hormone (FSH) in human serum and plasma.
   Abbott ARCHITECT® LH Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of human luteinizing hormone (LH) in human serum and plasma.
   Abbott ARCHITECT® Prolactin Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of prolactin in human serum and plasma.
   Abbott ARCHITECT® Progesterone Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of progesterone in human serum and plasma.
   Abbott ARCHITECT® Estradiol Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of estradiol in human serum and plasma.

2. Indication(s) for use:

   Abbott ARCHITECT® Estradiol Controls (LN 6C22) are devices intended for use in the ARCHITECT® Estradiol assay test system to eliminate test precision and to detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.
   Abbott ARCHITECT® Estradiol Controls (LN 2K25) are devices intended for use in the ARCHITECT® Estradiol assay test system to eliminate test precision and to detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.
   Abbott AxSYM Estradiol Controls are devices intended for use in the AxSYM® Estradiol assay test system to estimate test precision and toe detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the

diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.
Abbott FSH Controls are devices intended for use in the ARCHITECT, AxSYM, and IMx FSH test systems to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of follicle-stimulating hormone (FSH) in human specimens. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.
Abbott ARCHITECT® LH Controls are devices intended for use in the ARCHITECT LH assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of luteinizing hormone (LH) in human specimens. LH measurements are used in the diagnosis and treatment of gonadal function.
Abbott ARCHITECT® Prolactin Controls are devices intended for use in the ARCHITECT Prolactin assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of prolactin in human specimens. Prolactin measurements are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.
Abbott ARCHITECT® Progesterone Controls are devices intended for use in the ARCHITECT® Progesterone assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of pregesterone in human specimens. Progesterone measurements are used in the diagnosis and treatment of disorders of the ovaries or placenta.
Abbott ARCHITECT® Estradiol Calibrators are devices intended for use in the ARCHITECT® Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

3. Special condition for use statement(s):
   For prescription use

4. Special instrument Requirements:
   ARCHITECT *i* System, AxSYM System or IMx system.

I. Device Description:

Abbott Immunoassay/Clinical Chemistry Single Analyte Quality Materials (assayed) are devices intended for medical purposes for use in Abbott test systems to estimate precision and to detect systematic deviations that are used in the quantitative determination of values in the measurement of substances in human specimens.
Abbott ARCHITECT® Estradiol Calibrators are devices intended for medical purposes for use in Abbott test systems to establish points of reference that are used

in the quantitative determination of values in the measurements of substances in human specimens.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   IMx® Estradiol Controls
   Abbott FSH Controls
   AxSYM LH
   AxSYM Prolactin
   Abbott Immunoassay- MCC Control
   ARCHITECT® Estradiol Calibrators

2. Predicate k number(s):
   k951629
   k935612
   k935611
   k935675
   k990017
   k032458

3. Comparison with predicate:

ARCHITECT® Estradiol Control (LN 6C22)

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Estradiol	Estradiol
Reference	Standardized to an internal reference	Standardized to an internal reference
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	2 levels: 90 and 600 pg/mL	3 levels: 150, 500 and 1125 pg/mL

ARCHITECT® Estradiol Control (LN 2K25)

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Estradiol	Estradiol
Storage	2 to 8º C	2 to 8º C

Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	3 levels: 45, 190 and 600 pg/mL	3 levels: 150, 500 and 1125 pg/mL

AxSYM® Estradiol Control

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum	Serum
Analyte	Estradiol	Estradiol
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	3 levels: 85, 300 and 700 pg/mL	3 levels: 150, 500 and 1125 pg/mL

Abbott FSH Controls

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Follicle Stimulating Hormone	Follicle Stimulating Hormone
Level or Range	3 Levels: 5, 25 and 75 mIU/mL	3 Levels: 5, 25 and 75 mIU/mL
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**

ARCHITECT® LH Controls

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Luteinizing Hormone	Luteinizing Hormone
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	3 levels: 5, 40 and 80 mIU/mL are for 3.3-6.8, 27-53 and 54-106 mIU/mL respectively	3 levels: 5, 40 and 80 mIU/mL are for 3.5-6.5, 30-50 and 57-103 mIU/mL respectively

ARCHITECT® Prolactin Controls

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Prolactin	Prolactin
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	3 levels: 8, 20 and 40 ng/mL are for 6.2-9.8, 15.4-24.6 and 30.8-49.2 ng/mL respectively	3 levels: 8, 20 and 40 ng/mL are for 6-10, 16-24 and 32-48 ng/mL respectively

ARCHITECT® Progesterone Controls

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quality Control Material	Quality Control Material
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Progesterone	Progesterone
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	3 levels: 0.9, 5.0 and 217 ng/mL are for 0.6-1.2, 3.7-6.3 and 16.1-27.3 ng/mL respectively	3 levels: 1.1, 8.7 and 25.5 are for 0.9-1.3, 7.0-10.4 and 19.4-31.6 ng/mL respectively

ARCHITECT® Estradiol Calibrators

Similarities		
Item	**Device**	**Predicate**
Intended Use	Calibrator	Calibrator
Matrix	Serum or Plasma	Serum or Plasma
Analyte	Estradiol	Estradiol
Reference	Standardized to an internal reference	Standardized to an internal reference
Storage	2 to 8º C	2 to 8º C
Differences		
Item	**Device**	**Predicate**
Level and/or Ranges	6 Levels: 0, 50, 100, 250, 500 and 1000 pg/mL	2 Levels: 0 and 1600 pg/mL

K. Standard/Guidance Document Referenced (if applicable):

NCCLS Protocol EP5-T2.12

FDA Guidance for Industry "points to Consider Guidance Document on Assayed and Unassayed Quality Control Material" February 3, 1999.

L. Test Principle:

NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Abbott ARCHITECT® Estradiol (LN 6C22) precision was determined using 2 lots of reagents in replicates at two separate times per day for 20 days on two instruments. The average coefficients of variation for the first and second level was 6.48% and 3.05% respectively.

Abbott ARCHITECT® Estradiol Controls (LN 2K25) precision was determined using 3 control levels (low, medium and high) on three lots of reagents in replicates at two separate times per day for 20 days on two instruments. The average % coefficients of variation for the three levels were 6.56, 2.32 and 2.03%.

Abbott AxSYM® Estradiol Controls precision was determined using 3 controls (low, medium and high) on two instruments using 3 buffer-based panel members and 4 processed human serum-based panel members were analyzed in replicates at two separate times per day for 20 days with two lots. The average % coefficient of variation for the three levels were 9.95, 5.9, 6.85, 12.95, 8.93, 6.08 and 6.63% respectively.

Abbott FSH Controls precision was determined using 3 levels on two lots of reagents in replicates at two separate times per day for 20

days on two instruments. The average % coefficient of variation for the three levels were 4.03, 3.68 and 3.73%.

Abbott ARCHITECT® LH Controls precision was determined using 3 levels on two lots of reagents in replicates at two separate times per day for 20 days on two instruments. The average % coefficient of variation for the three levels were 3.6, 3.1 and 2.95%.

Abbott ARCHITECT® Prolactin Control precision was determined using 3 levels on one lots of reagents in replicates at two separate times per day for 20 days on two instruments. The average % coefficient of variation for the three levels were 4.55, 3.9and 4.45%.

Abbott ARCHITECT® Progesterone Controls precision was determined using 3 levels on two lots of reagents in replicates at two separate times per day for 20 days on two instruments. The average % coefficient of variation for the three levels were 5.58, 2.55 and 2.78%.

b. Linearity/assay reportable range:

NA

c. Traceability (controls, calibrators, or method)/stability:

Abbott ARCHITECT® Estradiol Controls (LN 6C22 and LN2K25) traceable to internal reference (secondary) standard.

Abbott AxSYM® Estradiol Controls are traceable to Abbotts manufactured internal reference (primary) standards for AxSYM Estradiol.

Abbott FSH Controls are traceable to a WHO FSH 2nd International Standard.

Abbott ARCHITECT® LH Controls are traceable to a WHO Luteinizing Hormone 2nd International Standard 80/522 at each concentration.

Abbott ARCHITECT® Prolactin Controls are traceable to a WHO Prolactin 3rd International Standard 84/500 for each concentration.

Abbott ARCHITECT® Progesterone Controls are traceable to a progesterone USP standard.

Abbott ARCHITECT® Estradiol Calibrators are traceable to an Abbott Internal Reference Standard.

Stability: Real time stability studies have been conducted and the expiration for each of the control/calibrator is listed below.

Abbott ARCHITECT® Estradiol Controls (LN 6C22)- 10 months

Abbott ARCHITECT® Estradiol Controls (LN 2K25)- 9 months

Abbott AxSYM® Estradiol Controls- 10 months

Abbott FSH Controls-15 months

Abbott ARCHITECT® LH Controls- 10 months

Abbott ARCHITECT® Prolactin Controls- 4 months
Abbott ARCHITECT® Progesterone Controls- 12 months at -10° C and 21 days at 2-8° C.

d. Detection limit:
NA

e. Analytical specificity:
NA

f. Assay cut-off:
NA

2. Comparison studies:
   a. Method comparison with predicate device:
   NA
   b. Matrix comparison:
   NA

3. Clinical studies:
   a. Clinical sensitivity:
   NA

   b. Clinical specificity:
   NA
   c. Other clinical supportive data (when a and b are not applicable):
   NA

4. Clinical cut-off:
   NA

5. Expected values/Reference range:
   Refer to the package insert for the assigned values and ranges.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.